

**REMARKS**

Claims 1-17 and 19-29 were pending in the application; claims 3-6, 22, and 23 are withdrawn. Support for claim 1 amendment is on page 7, lines 18-22 and page 12, lines 9-11 of the originally filed application. No new matter is entered herein.

**I. 35 USC § 103(a)****A. Claims 1, 2, 8-17, 19-21, 25-27, and 29**

Claims 1, 2, 8-17, 19-21, 25-27, and 29 were rejected under 35 USC § 103(a) as allegedly being unpatentable over Andersson *et al.* (US2003/0053934; “Andersson”) in view of Yager *et al.* (US. 2003/0124623; “Yager”).

Despite the clarity of the term “bed preserving agent,” the submitted amendment was made without prejudice and without acquiescence to clarify the function of the agent in the solid phase material of the microfluidic device, *i.e.* to permit the solid phase material in a wet state to be transformed to a dry state, and after storage and transportation of the device be reconstituted to wet beds having essentially the same performance as wet beds of the same solid phase material not having been transformed to the dry state.

Thus, in certain embodiments of the invention when preparing a microfluidic device of the present invention, the solid phase material is applied to the device in wet form and then dried to be subsequently reconstituted in wet form when used. The procedures of pre-dispensing, drying, storage, transportation, reconstitution *etc.*, of the solid phase may, however, cause several adverse effects to the material, including unacceptable formation of channels, cavities, air inclusions, as well as escape of solid phase material from a desired location within a microchannel structure.

Further, in these microfluidic devices, the binding of the solute to a porous bed in a microfluidic device is typically monitored by spectrometric methods through a detection window associated with the porous bed, *i.e.* detection directly on the column. It is readily seen that the creation of undesired channels, cavities and air inclusions will increase the noise level for detection and also reduce sensitivity and reproducibility.

According to embodiments of the present invention, the above-mentioned adverse effects on the solid phase bed during its transformation and storage/transportation phases may be at least considerably reduced by including in the wet solid phase material before drying or dehydration, a bed preserving agent having the desired bed-preserving capabilities, *i.e.* to provide for the bed having the essentially the same performance after drying and reconstitution as before drying.

According to the Examiner, it would be obvious to a person skilled in the art to incorporate into the packed bed in Andersson a “preservative” such as, *e.g.*, trehalose, as described by Yager to thereby render reactants in the device of Andersson in a solid and dry state, such that the device may be stored in conjunction with reagents in a robust manner, and thereby arrive at a microfluidic device of the present invention. Yager describes a microfluidic device with one or more storage areas, each of which has fixed therein a dissolvable solid reagent plug comprising reagent dispersed in a matrix of a dry but soluble “preservative” such as carbohydrate, *e.g.*, sugar such as trehalose.

Applicants respectfully assert that the skilled artisan would not consider it obvious to include a preservative in the solid phase with immobilized affinity reactant according to Andersson for any reason, including to stabilize the immobilized reactants in a solid and dry state, because there is no mention in Andersson of drying the solid phase or the solid phase being in a dry state and therefore no potential need of any stabilizing of the reactants. Secondly, the skilled artisan would not consider it obvious to apply the teaching of Yager, which is to prepare a dissolvable plug of reactant within a matrix of a preservative, to an insoluble solid phase particle bed with immobilized reagent as in Andersson.

Even more so, it would not be obvious to add a “reagent preservative” to a solid phase bed to obtain the bed-preserving effects aimed at in the present invention, because no problems with solid phase material beds are mentioned at all in either of Andersson and Yager. In this regard, it is noteworthy that the solid phase bed in the microfluidic device according to the present invention need not support any immobilized reagent; see *e.g.* page 15, lines 30-32 and page 24, lines 13-15.

The Examiner notes on pages 7-8 of the Action that the Action was not considered final, because no explanation for a motivation was clearly addressed but that the motivation comes from Yager. This seems backwards, as why would the skilled artisan even look to Yager as a source for preservation of the porous bed if the skilled artisan reading Andersson has no need to preserve it? Applicants assert that there is no reason to seek resolution of an unrecognized problem. Andersson makes no consideration that an agent to preserve the bed would be necessary, and the courts have determined that an invention is not obvious when there was no reason identified that would have led the skilled artisan to make the modification. *Takeda Chemical Industries, Ltd. V. Alphapharm Pty. Ltd.*, 492 F.3d 1350, 83 USPQ2d 1169 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1739 (2008).

Applicants therefore respectfully assert that the present invention as claimed is patentable over the combination of Andersson and Yager and respectfully request withdrawal of the rejection.

#### **B. Claims 7, 24, and 28**

Claims 7, 24, and 28 were rejected under 35 USC § 103(a) as allegedly being unpatentable over Andersson in view of Yager and further in view of Glezer *et al.* (U.S. 2004/0189311).

Applicants address above the rejection over the combination of Andersson and Yager and assert that Glezer fails to teach, suggest, or provide motivation for the subject matter that is lacking in the combination of Andersson and Yager.

Applicants respectfully request withdrawal of the rejection.

## **II. Double Patenting**

Claims 1, 8, and 16-17 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of co-pending Application No. 10/550,182.

As in the Response filed October 27, 2010, Applicants submit that they have acknowledged the provisional double-patenting rejections and, further, that it is clear Applicants are not required to address the merits of the provisional double-patenting

rejections until such time as the co-pending application(s) issue and the rejections are made non-provisional.

### **III. Conclusion**

Applicants assert that the pending claims are suitable for allowance and respectfully request withdrawal of all rejections.

Applicant believes no fee is due with this response other than the fee for the Petition for Extension of Time of Three Months. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02773US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

By\_\_\_\_/Melissa L. Sistrunk/\_\_\_\_\_  
Melissa L. Sistrunk  
Registration No.: 45,579  
FULBRIGHT & JAWORSKI L.L.P.  
Fulbright Tower  
1301 McKinney, Suite 5100  
Houston, Texas 77010-3095  
(713) 651-3735  
(713) 651-5246 (Fax)  
Agent for Applicant